Reviewer: John P. Knezovich, PhD
Date: 3/14/10

Review of the Draft Report: Lambda-Cyhalothrin Criteria Derivation
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Overview
Freshwater criteria for Lambda-cyhalothrin (L-cyhalothrin) defined in this draft report was derived using methodology recently developed by Tenbrook *et al*. (2009)[1]. The methodology considers relevance of the endpoints and quality of the data in derivation of the criteria. This methodology was motivated by the California Regional Water Quality Control Board's desire to employ rigorous methods to develop criteria for protection of the Sacramento and San Joaquin River Watershed.

Basic information and physical-chemical data
The report provides a comprehensive summary of the physical-chemical data for L-cyhalothrin. This data set indicates that this pesticide has high Kow, low volatility, high potential to bioaccumulate, high potential to sorb to sediments, and is persistent in aqueous environments (i.e., low rates of hydrolysis, photolysis, and biodegradation). Accordingly, this pesticide's physical-chemical characteristics make its exposure to aquatic organisms a relevant concern, due to its persistence and high potential for bioaccumulation and food-web transfer.

Human and wildlife dietary values
The FDA has not set action levels for L-cyhalothrin in fish tissue but has set a level for hog meat hogs at 0.1 mg/kg. Toxicity to mallard ducks is low, with an LC_{50} (which should be reported as an LD_{50}) value for food of 3,948 mg/kg in 8-day old ducks. Another study, however, indicated no toxicity at an equivalent dose in food. It needs to be mentioned that this latter study was conducted with adult ducks. The reported NOEL of 30 mg/kg is deceptive as this is the highest dose that was tested (e.g., the NOEL could be significantly higher than this value). The authors correctly point out that a LOEL could not be determined for this reason.

Ecotoxicity data and data reduction
The authors evaluated approximately 65 published studies of L-cyhalothrin toxicity to develop the proposed criteria. Relevance was determined using the aforementioned methods[1] and only data for studies that were deemed acceptable were used in the criteria derivation. Adequate and reliable data was available for determining acute toxicity using animal studies and exclusion criteria appear to have been applied properly. Twenty acute, 3 chronic and 8 microcosm and ecosystem studies were used to support criteria development calculations. Four studies of effects on wildlife were reviewed for relevance to bioaccumulation.
Data was excluded using proper criteria ensuring analysis of properly conducted experiments and sensitive life stages.

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[1] P. Tenbrook *et al*. (2009). *Methodology for derivation of pesticide water quality criteria for the protection of aquatic life in the Sacramento and San Joaquin River basins. Phase II: Methodology development and derivation of chloropyriphos criteria.* Report prepared for the Central Valley Regional Water Quality Control Board, Rancho Cordova, CA.

Acute criterion calculation
The acute criterion for L-cyhalothrin was calculated using methods defined by Tenbrook *et al*. (2009). Data for all five required taxa was available and a criterion of 1 ng/L was derived using acceptable calculations and rounding to significant digits.

Chronic criterion calculation
The acute-to-chronic ratio (ACR) method was used to derive the chronic criterion using data for only two of the five required taxa. The chronic values for these two taxa (i.e., warm water fish and planktonic crustacean) were paired with acute data that included a saltwater species, which was appropriate for inclusion in this calculation according to the referenced method. However, the statement that "freshwater and saltwater ACRs have been shown to be comparable" does not appear to be supported by this data, as the saltwater ACR of 2.6 is substantially lower than the values for the freshwater species (i.e., 4.9 and 8.2). Accordingly, the inclusion of the saltwater ACR in this calculation requires a stronger justification.

A final chronic criterion of 1 ng/L was calculated using the median 5th percentile value that was divided by the multi-species ACR. This calculation appears to have been performed correctly although the raw criterion value of 0.0005144 µg/L should be 0.0005142 µg/L, which are both rounded to the same value of 1 ng/L.

Bioavailabilty
Because L-cyhalothrin has a high Kow, it will have a high affinity for dissolved organic and particulate phases in aquatic environments. The statement is made that toxicity is believed to occur primarily from the *portion* of the compound that is dissolved in the water. The phrasing of this sentence implies that a molecule of L-cyhalothrin can be partially dissolved. Instead, the authors should use the word *fraction* when distinguishing between soluble and sorbed phases. The conclusion that the dissolved phase of L-cyhalothrin is the primary bioavailable phase is consistent with data for compounds with similar physical/chemical characteristics.

Many studies support the conclusion that sorption of L-cyhalothrin to organic phases that are present in aquatic environments reduces its bioavailability to aquatic organisms. This effect is consistent with the behavior of other compounds that have similarly high Kows. An evaluation of the work conducted by Smith and Lizotte (2007) concludes that the equations that they developed to account for L-cyhalothrin toxicity in the presence of binding agents (e.g., TSS, DOC) could be used to predict toxicity for the species that was used in these tests (*H. azteca*). The authors dismiss the use of this approach because it was only derived for a single species. However, they should also point out that natural environments contain not one, but several sorbents, which renders this approach non-viable for natural waters.

The authors are correct in stating that it is not practical to recommend that the "freely-dissolved" phase of L-cyhalothrin be used for compliance purposes. Instead, isolation of the dissolved phase by solid-phase micro-extraction presents a practical approach for approximating the bioavailable phase of L-cyhalothrin. Determination of site-specific dissolved concentrations of L-cyhalothrin is not practical due to the need for accurate measurements of dissolved organic compounds and suspended solids, which require significant effort to acquire. The fact that these parameters can vary spatially and temporally further complicates such assessments and should be mentioned here.

Nominal (i.e., added concentrations) are likely to over-estimate exposure concentrations due to sorption of L-cyhalothrin to organic phases as well as container surfaces (this effect has the result of under-predicting toxicity). Accordingly, the authors recommend that criteria compliance be based on whole-water concentrations of L-cyhalothrin, as this will provide a conservative (i.e., over-protective) estimate of this compound's availability. This is a prudent recommendation given uncertainties in reported exposure concentrations.

Mixtures
Because L-cyhalothrin often occurs in the presence of other pyrethroid insecticides that have a similar mode of action, the toxic unit or relative potency factor approaches are appropriate to use. However, compounds that have dissimilar modes of action may exhibit additive, synergistic, or antagonistic effects in the presence of L-cyhalothrin. The conclusion that non-additive effects cannot be used for criteria compliance is appropriate due to the lack of a robust predictive model.

Temperature, pH effects
An inverse relationship between pyrethroid toxicity and water temperature is well documented. This relationship is important as laboratory toxicity tests are often conducted at temperatures that are higher than those in natural ecosystems. Although sufficient data does not exist to enable accurate predictions of temperature-related toxicity due to L-cyhalothrin in aquatic ecosystems, this relationship should be considered in the derivation of safety factors as it is likely that criteria derived from laboratory studies conducted at relatively high temperatures will under-predict toxicity in many natural environments.

Sensitive species
The calculated acute criterion of 1 ng/L is below all of the acute values on the data set. However, the lowest acute value of 2.3 ng/L (for *H. azteca*) is reported as an LC_{50}, which indicates that toxic effects will occur for this species at lower concentrations. This issue must be addressed. In addition, the MATC of 0.32 ng/L reported for *M. bahia* is dismissed because this is a saltwater species. Although fresh and saltwater species may have different sensitivities to L-cyhalothrin, no evidence is presented to specifically support this claim. As a result of these factors, a more rigorous evaluation of potential impacts of L-cyhalothrin on sensitive species is warranted.

Ecosystem and other studies
The authors reviewed 5 studies of microcosm and ecosystem tests that had acceptable ratings. In each of these studies, toxicity was only reported for water concentrations that were higher than the proposed acute and chronic criteria. A study conducted by Lauridsen and Friberg (2005) reported toxic effects to *G. pulex* at a L-cyhalothrin concentration of 1 ng/L, which is equal to the proposed criteria. This study was presumably given a low reliability rating because only nominal values for L-cyhalothrin were reported. The authors state that the measured concentration may have been significantly lower than the nominal value, which is likely due to

loss of L-cyhalothrin due to sorption. However, such a loss would serve to increase the apparent toxicity of L-cyhalothrin in this system. In other words, it would be toxic at a concentration lower than 1 ng/L. This study should not be dismissed without a more thorough examination of its implications.

Threatened and endangered species

Data on L-cyhalothrin toxicity is available for two threatened or endangered fish species (*O. mykiss* and *G. aculeatus*). Both of these species have toxicity values that are significantly higher that the proposed criteria. The EPA's interspecies correlation estimation method was used to estimate toxicity values for listed animals that are members of the same family or genus as organisms in the data set. These calculations produced values that were significantly higher than the proposed criteria.

Data for plants were not in the data set and specific conclusions could not be offered for these species. Overall, the proposed criteria would appear to be protective of threatened and endangered species.

Bioaccumulation

L-cyhalothrin has a high K_{ow} and therefore a high potential to bioaccumulate in aquatic organisms. Reported bioconcentration factors are consistent with this K_{ow} and a bioaccumulation factor (BAF) approach was used to estimate the water concentration of L-cyhalothrin that would result in a lethal concentration in wildlife that would consume contaminated fish. An LD_{50} value was used for this calculation because a meaningful NOEL for mallards does not exist. The resulting formula is awkward because it uses a lethal concentration to calculate an NOEC. Nevertheless, using this approach, a water concentration of 176 ng/l would be required to produce a body burden of L-cyhalothrin in fish that would be lethal to 50% of a mallard population (i.e., not an NOEC). Although a true NOEL for mallards does not exist, a no-effect concentration based on the highest dose (i.e., 30 mg/kg) used by Beavers *et al.* (1990) would result in a water concentration of 1.3 ng/L, which is essentially equivalent to the proposed criteria. The true NOEC would therefore appear to lie between 1.3 and 176 ng/L. For the sake of completeness, this range for the "true" NOEC should be discussed in the final report.

Using tolerance levels for L-cyhalothrin in meat (i.e., 0.1 mg/kg) that would be protective of human health, an equivalent concentration in fish would require a water concentration of 18 ng/L. It should be mentioned that the water concentrations of L-cyhalothrin that would be required to cause concern for food-web transfer would likely result in acute toxicity to fish and aquatic invertebrates.

Harmonization with air and sediment criteria

Sediment and air quality standards for L-cyhalothrin do not exist. Partitioning into the water column could serve as a proxy for sediment burdens.

Assumptions, limitations, and uncertainties

The authors correctly point out that the major source of uncertainty in this evaluation stems from the lack of viable L-cyhalothrin toxicity data for three of the five required taxa. The approaches used (i.e., ACR and Assessment Factor) were appropriate given this limitation. However, the lack of chronic data for *H. azteca* is cause for concern as this is the most sensitive species for acute effects. Coupled with the potential heightened sensitivity of this species at low water temperatures, it is possible that the proposed chronic criterion would not be protective under all environmental conditions. Although the authors are correct to point out that an application of an additional safety factor has merit, there is little discussion of how such a factor could or should be derived. At minimum, a more thorough description of temperature effects derived from the Weston *et al*. (2008) study would be appropriate.

Comparison to national standard methods
EPA (1985) methods were also used to derive acute and chronic criteria for L-cyhalothrin. All required elements of the EPA method could not be met because data for organisms that are not chordates or arthropods is not in the data set. The authors used proper caveats and calculations in performing this analysis (i.e., they used 7 of the 8 requirements as did Cal Fish & Game).

The acute criterion proposed in this study is essentially the same as that derived by the EPA method (1 ng/L vs. 0.9 ng/L, respectively). The slight difference between these values appears to be due to the fact that the EPA method included data for studies that did not meet the quality requirements used in this study.

The chronic criterion derived in this study (1.0 ng/L) is a factor of 2 higher than that derived using the EPA methodology (0.4 ng/L). Although both approaches yield acute values that are similar, the slight differences are inflated when the acute values are divided by the same ACR value of 4.73. This apparent difference is an artifact of the approach used for rounding. For example, if the final acute values of 2.43 ng/L and 1.84 ng/L are rounded prior to being divided by the safety factor, they yield the same number (i.e., 2 ng/L) and hence the same acute criterion (1.0 ng/L). Likewise, the rounded final acute values divided by the ACR yield the same chronic value of 0.4 ng/L. Because the rounding has such a profound effect on the final chronic value, the authors need to re-examine this approach and provide a strong rationale for the rounding method that they used.

Final L-cyhalothrin *criteria statement*
Based on the best available data, the acute criteria of 1 ng/L proposed in this report should be protective of aquatic species in the Sacramento and San Joaquin River basins. However, the chronic criteria needs to be re-evaluated and justified in light of calculation approaches that can result in the proposed value being high. This results from the relatively small differences in acute data that may be magnified due to mathematical rather than biological reasons. Both criteria should be re-evaluated as soon as additional data for sensitive species (acute and chronic) and temperature effects becomes available.